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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/793,833	02/18/97	SCHUMACHER J	69430

13M1/1017

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EXAMINER	
BEISNER, W	

ART UNIT	PAPER NUMBER
1303	

DATE MAILED: 10/17/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/793,833	Applicant(s) SCHUMACHER ET AL.
	Examiner William H. Beisner	Group Art Unit 1303

☒ Responsive to communication(s) filed on *Jul 7, 1997* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-28* is/are pending in the application.

Of the above, claim(s) *1-6 and 23-28* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *7-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6 and 7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group II, Claims 7-22, in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-6 and 23-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 5.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

4. The information disclosure statements filed July 15, 1997 (Paper No. 6) and July 24, 1997 (Paper No. 7) have been considered and made of record.

Drawings

5. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. See form PTO-948 attached to Paper No. 4.

Specification

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

7. The disclosure is objected to because of the following informalities:

The specification does not include the section headings as shown below. The specification also does not include a "Brief Description of the Drawings".

Appropriate correction is required.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

(a) Title of the Invention.
(b) Cross-References to Related Applications (if any).
© Statement as to rights to inventions made under Federally-sponsored research and development (if any).

(d) Background of the invention.
   1. Field of the Invention.
   2. Description of the Related Art including information disclosed under 37 CFR 1.97-1.99.

(e) Summary of the Invention.

(f) Brief Description of the Drawing.

(g) Description of the Preferred Embodiment(s).

(h) Claim(s).

(i) Abstract of the Disclosure.

Claim Rejections - 35 USC § 112

8. Claims 7-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Throughout claims 7-22 use of the phrase "characterized in that" is indefinite in view of the fact that the metes and bounds of the claim cannot be clearly determined. That is, is the claim language inclusive or exclusive. It is suggested that acceptable U.S. claim language such as "comprising" or "consisting" be employed so as to clearly define the claimed invention.

In claim 7, "such enzyme inhibitors" and "the sample" lack antecedent basis. Also, it is not clear if the claim intends to recite the vessel as part of the claimed device. Currently the claim merely recites a valve/pump arrangement so as to fill at least on test vessel. This language means that the arrangement is connected such that a vessel can be filled. The vessel has not been positively recited as part of the claimed device. Finally, the recited detector is indefinite because it

is not clear how this device structurally cooperates with the rest of the positively recited structures of the device. Note, the cleavage product is not discussed previously in the claim.

In claim 10, "the sample supply tube" and "the sampler" lack antecedent basis.

In claim 19, "the trial test vessel" lacks clear antecedent basis.

In claim 22, "the column buffer"; "the degree of dilution" and "the trial vessels" all lack antecedent basis.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 7-9, 18 ,19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Showa Denko Kabushiki Kaisha (EP 0 329 190).

The reference of Showa discloses a device for detecting the activity of enzymes which includes a column, 6, filled with a substance which is capable of removing enzyme inhibitors; a valve/pump arrangement, 1 and 2, in series with the column, 6; a test vessel, 4; temperature control structure, 3; and a detector, 5, which can be a fluorimeter (See column 7, lines 10-24). Column, 6, is capable of being used repeatedly and/or is capable of being exchanged.

11. Claims 7-9, 16, 17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Regnier et al.(US 4,243,753).

The reference of Regnier et al. discloses a device for detecting the activity of enzymes which includes a column, 14, filled with a substance which is capable of removing enzyme inhibitors; a valve/pump arrangement, 26, 25, 21, 19, in series with the column, 14; a test vessel, 15; and a detector, 30. Note, column, 15, functions as a mixing device and the pump/valve and piping system provides the required experimental conditions.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 7-9, 18, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Showa Denko Kabushiki Kaisha (EP 0 329 190) in view of Koohmaraie et al.(J. Anim. Sci.).

The reference of Showa has been discussed above.

If it is determined that the column, 6, of the reference of Showa is not inherently "capable of binding such enzyme inhibitors which correspond to at least one enzyme in the sample", the reference of Koohmaraie et al. discloses that it is known in the art to measure the activity of a specific enzyme in a sample wherein the sample is first contacted with a column of Sepharose so as to remove inhibitors of the enzyme to be detected.

As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to perform the method of Koohmaraie et al. for the known and expected result of providing a system recognized in the for performing the method of the reference of Koohmaraie et al. since both references are drawn to

the detection of enzyme activities wherein the sample is first treated to remove an inhibitor substance.

15. Claims 7-9, 16 , 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regnier et al.(US 4,243,753) in view of Koohmaraie et al.(J. Anim. Sci.).

The reference of Regnier et al. has been discussed above.

If it is determined that the column, 14, of the reference of Regnier is not inherently "capable of binding such enzyme inhibitors which correspond to at least one enzyme in the sample", the reference of Koohmaraie et al. discloses that it is known in the art to measure the activity of a specific enzyme in a sample wherein the sample is first contacted with a column of Sepharose so as to remove inhibitors of the enzyme to be detected.

As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to perform the method of Koohmaraie et al. for the known and expected result of providing a system recognized in the for performing the method of the reference of Koohmaraie et al. since both references are drawn to the detection of enzyme activities wherein the sample is first treated to remove an inhibitor substance.

16. Claims 10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Showa Denko Kabushiki Kaisha (EP 0 329 190) or Regnier et al.(US 4,243,753) alone or in view of Koohmaraie et al.(J. Anim. Sci.) and further in view of Stevens (US 4,762,617).

The references of Showa and Regnier et al. alone and/or in view of Koohmaraie et al. have been discussed above.

Claims 10 and 22 differ by reciting that the sample and buffer are alternatively supplied to the column and that the system is automatically controlled by a computer device.

The reference of Stevens discloses a system for introducing a sample into a separation column wherein the buffer and sample are alternatively supplied and the system is controlled by a computer device.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to automate the operation of the systems of the primary reference by using a computer control. With respect to the sample supply, use of a sample supply system as disclosed by the reference of Stevens would have been obvious for the known and expected result of providing a means recognized in the art for automating the addition of a plurality of different samples to the detection system.

Allowable Subject Matter

17. Claims 11-15 and 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

18. The following is a statement of reasons for the indication of allowable subject matter:

The above claims would be allowable because the prior art of record fails to teach or fairly suggest the claimed combination of elements which includes i) a control device connected within the system so as to check the purity of the buffer discharged from the column or ii) a means for measuring the degree of dilution of the discharged sample caused by the buffer of the column or iii) a switching valve provided within the system such that sample can alternatively pass through the column or bypass the column in order to get to the test vessel.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following prior art references are cited as being of interest:

Muramatsu et al.(US 4,260,680); Luong et al.(US 5,411,866); Sekisui Chemi (JP 59-6897); Olympus Optical (JP 60-164476); and Unitika (JP 61-122565).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **William H. Beisner** whose telephone number is **(703) 308-4006**. The examiner can normally be reached on Tuesday to Friday from 6:40 AM to 4:10 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Don Czaja, can be reached on (703) 308-3852. The fax phone number for this Group is (703) 305-7115.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

William H. Beisner
Primary Examiner
Group 1300
10/13/97